UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,335	01/02/2002	Ronnie C. Hanecak	ISIS-4976	7737

34138 7590 11/29/2004

COZEN O'CONNOR, P.C.
1900 MARKET STREET
PHILADELPHIA, PA 19103-3508

EXAMINER	
GUZO, DAVID	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 11/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,335	HANECAK ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *8-10* is/are allowed.

6)☒ Claim(s) *11-15 and 20-22* is/are rejected.

7)☒ Claim(s) *16-19, 23-26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

The Declaration filed 7/22/04 is acceptable and has been entered.

35 USC 112, 1st Paragraph Rejections

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The rejection as it pertains to Claims 11-13 is maintained for reasons of record in the previous Office Action (Mailed 3/25/04) and for reasons outlined below. It is noted that the only disclosed use for the claimed method of modulating the effects of aging of a mammalian cells appears to involve inhibiting the aging process *in vivo*. It is also again noted that applicants provide no uses for a method of modulating the effects of aging in a mammalian cell *in vitro*.

Applicants traverse of the outstanding 35 USC 112, 1st paragraph (enablement) rejection of the composition claims and method claims 8-10 is persuasive. It is noted that Claims 8-10 recite a method for inhibiting the division of a malignant mammalian cell comprising administering the recited modified oligonucleotides such that telomere

length is modulated. Applicants' arguments in the response filed 9/17/04, deals almost exclusively with arguments directed at use of oligonucleotides to treat cellular malignancies. The references cited by applicants to bolster their arguments deal with use of antisense oligonucleotides to treat malignancies. The examiner notes that post filing art indicates that oligonucleotides containing the G-quartet motifs have been shown to have activity against certain tumors.

Applicants however present no arguments, data or cite any references which would provide evidence that administering the instant oligonucleotides would act to modulate the effects of aging of mammalian cells in an organism. Applicants' specification provides no teachings on any specific oligonucleotides which would be able to modulate cellular aging in any mammal and the specification provides no data on concentrations of oligonucleotides to be administered which would be sufficient to modulate cellular aging in a mammal. In an research area where no one has been able to demonstrate success in slowing or retarding aging in an organism using oligonucleotides, the lack of any specific teachings with regard to enablement of the claimed invention renders the specification as merely an invitation for the skilled artisan to attempt to modulate cellular aging in an organism using trial and error experimentation.

Applicants present no arguments traversing the examiner's statement that methods of inhibiting the effects of aging in cells *in vivo* using oligonucleotides which can modulate telomeres length has, as far as the examiner has been able to determine from a search of the prior art, **not even been seriously contemplated**. Indeed, the

basis premise of applicants' concept of telomere length being correlated with aging may not be scientifically supportable. Recent research (as reviewed by DeMagalhaes et al., Rejuvenation Research, 2004, Vol. 7, No. 2, pages 126-133) indicates that "No connection exists between mean telomere length and mammalian aging." (p. 128 of DeMagalhaes et al.). While the examiner acknowledges that countless people through the ages have dreamed of finding a way to avoid or slow aging, it must be considered that applicants' disclosure, coupled with what is known in the art does not enable the skilled artisan to stop or slow cellular aging in a human or other mammal.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14-15 and 20-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-21 and 23 of U.S. Patent No. 5,952,490. Although the conflicting claims are not identical, they are not patentably distinct from each other because the modified oligonucleotides claimed in

the '490 patent are encompassed within the instantly claimed subject matter. The modified oligonucleotides claimed in the '490 patent are species encompassed within the broad formula recited in instantly recited claims 14 and 21. For example, the phosphorothioate oligonucleotide TTGGGGTT claimed in the '490 patent is encompassed within the instant formula and is specifically contemplated by applicants as an oligonucleotide expected to result in modulation of telomere length (see specification, p. 14, Table 1). Likewise, the modified oligonucleotides recited in the '490 claims as having the formula TxG4Ty wherein x and y can be 2 or 3 or claims reading on oligonucleotides are encompassed within the instant formula. The claims of the '490 patent would anticipate the claimed invention.

Claims 14-15 and 20-22 are directed to an invention not patentably distinct from claims 17-21 and 23 of commonly assigned 5,952,490. Specifically, the claims are not patentable distinct for the reasons recited in the above Obviousness Type Double Patenting Rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned US 5,952,490, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c)

and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Claims 8-10 are allowed.

Claims 16-19 and 23-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
November 27, 2004